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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/873,500

06/04/2001

John E. Ware

QMET-201

5112

24972 7590 04/06/2009  
FULBRIGHT & JAWORSKI, LLP  
666 FIFTH AVE  
NEW YORK, NY 10103-3198

EXAMINER

LE, LINH GIANG

ART UNIT

PAPER NUMBER

3686

MAIL DATE

DELIVERY MODE

04/06/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 09/873,500	<b>Applicant(s)</b> WARE ET AL.	
	<b>Examiner</b> MICHELLE LE	<b>Art Unit</b> 3686	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 January 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 18-23, 25-27, 29-34, 39, 40, 43 and 46-67 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 18-23, 25-27, 29-34, 39-40, 43, and 46-67 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12 January 2009 has been entered. Claims 18-23, 25-27, 29-34, 39-40, 43, 45 and 46-67 remain pending.

### ***Claim Rejections - 35 USC § 101***

2. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. The claimed invention is directed to non-statutory subject matter. Claims 18-23, 25-27, 29-34, 39-40, 43, 45 and 46-67 are rejected as being directed to non-statutory subject matter.

Independent claims 18 and 47 are directed towards a computer based system for assessing the health status or health care of a patient not defined by components of a

system recognized under 35 USC 101. Under *In re Nuijten*, 500 F.3d 1346 (Fed. Cir., 2007), the construction of machine is defined as a "concrete thing, consisting of parts, or of certain devices and combination of devices [including] every mechanical device or combination of mechanical powers and devices to perform some function and produce a certain effect or result." (Quoting *Burr v. Duryee*, 68 U.S. (1 Wall.) 531, 570 (1863)). "A "module" is not a concrete thing and a software term thus is not recognized as a system component. Furthermore, Applicant defines a "module" as synonymous with a process for test generation, testing or administering, evaluating and reporting (Specification; pg. 14).

Furthermore independent claims 18 and 47 fail to be statutory under 35 USC 101 as they are directed towards functional descriptive material not clearly on any medium. Under the teachings of *In re Lowry*, 32 F.3d 1579 (Fed. Cir., 1994), a claim to software or functional descriptive material is only statutory if clearly on a medium.

Independent claims 39 and 63 are also directed to non-statutory subject matter as they do not fit into any of the four statutory classes. Independent claims 39 and 63 are directed to computer readable media but the claims and specification fails to clearly define what type of media it is. Thus Examiner cannot ascertain which statutory class Applicant's claims are directed towards.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 18-23, 25-27, 29-34, 39-40, and 46-50 and 52-67 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Ware et al. (Ware, Jr., John E., Jakob Bjorner, and Mark Kosinski, Dynamic Health Assessments: The Search for More Practical and More Precise Outcomes Measures, The Quality of Life Newsletter, January 1999-April 1999), in view of Lewis (5,059,127) for the reasons set forth in the 2/11/08 Final Rejection and 7/14/08 Examiner's Answer. Applicant has added the limitation of varying the threshold and modifying the test during the administration of the test. Examiner believes Ware and Lewis are still applicable as they teach varying thresholds (Ware; pg. 11, col. 3, par. 2; pg. 12 Col.1-2; pg. 13 Col. 1-2) and dynamically modifying a test (Lewis; Col. 6, "Random vs. Optimum Selection") during the administration of a test.

6. Claims 43, 45, 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ware et al. (Ware, Jr., John E., Jakob Bjorner, and Mark Kosinski, Dynamic Health Assessments: The Search for More Practical and More Precise Outcomes Measures,

The Quality of Life Newsletter, January 1999-April 1999), in view of Bair (6,067,523) for the reasons set forth in the 2/11/08 Final Rejection and 7/14/08 Examiner's Answer.

7. Newly added claims 46-50, and 52-67 further repeat limitations of the previously presented claims and thus the reasons for rejections are incorporated herein.

### ***Response to Arguments***

8. Applicant's arguments filed 12 January 2009 have been fully considered but they are not persuasive.

9. It is noted that Applicant repeats arguments from previous actions thus Examiner incorporates rebuttal to these arguments from the 2/11/08 Final Rejection and 7/14/08 Examiner's Answer.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHELLE LE whose telephone number is (571) 272-8207. The examiner can normally be reached on 8 AM - 5PM, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jerry O'Connor can be reached on (571) 272-6787. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or (571) 272-1000.

3/28/09  
/M. L./  
Examiner, Art Unit 3686

/Gerald J. O'Connor/  
Supervisory Patent Examiner  
Group Art Unit 3686